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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,552	MECKING ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *26-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/06; 1/28/04; 6/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The new Examiner of record acknowledges Applicant's election with traverse of Group I claims 1-25 for prosecution on the merits. The Examiner also acknowledges Applicant's election of polyethyleneimine and silver nanoparticles. Applicant asserts that an "appropriate explanation" as to the existence of a serious burden has been omitted and that since both inventions groups I and II fall under the same class and subclass then it would not be a serious burden to search both inventions. The present Examiner cannot agree. First of all, the prior Examiner of record did not classify the inventions. Invention group I can be classified as 424/422, 423, 618. Invention group II can be classified as 424/78.08+. The prior Examiner of record directed Applicant's attention to US 2005/0058844 which discloses a method of making a polyacrylic acid-PEI silver compound coating on a silicone wafer with silver nanoparticles which is a materially different product than instantly claimed (See Example 3, [0173-0177] and claims 6-9). Therefore, the prior Examiner met his burden of establishing distinctness and the present Examiner has shown different subclasses for the inventions. It can only be concluded that it would be a serious burden on the Examiner to search both inventions. The restriction is maintained and made FINAL.

Claims 26-33 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-22 are presented for examination on the merits.

Comment: Independent claims 1 and 21 should read: --- A medical-technology product.... --- and dependent claims should be amended to: --- The medical-technology product... ---.

Comment: Claim 1 recites: "at least on the surface and on the surface at least on a portion of the surface." This is awkward and perhaps redundant. When the layer is on the surface is it not then on a portion of the surface? The Examiner requests clarification.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed January 28, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because reference AO is not legible and in a foreign language. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art,* (2) *partial structure,* (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention.*

While all of the factors have been considered, only those required for a *prima facie* case are set forth below.

The specification discloses branched amphiphilic macromolecules and metal nanoparticles, are suitable for use according to the invention. The specification discloses amidated polyethyleneimine as the branched amphiphilic macromolecule and silver salts and copper salts as the metal compounds to form the metal nanoparticles. The only example of a "medical technology product" is a glass slide [44].

The claims are drawn to a medical technology product with a layer of a hybrid complex material composed of a branched amphiphilic macromolecule and of a metal nanoparticle at least on the surface. **Let the Examiner be clear: there is insufficient written description for the branched amphiphilic macromolecule and of the metal nanoparticle.**

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the written description inquiry, is

whatever is now claimed (see page 1117). A review of the language of the claim indicates that these claims are drawn to a genus, i.e., branched amphiphilic macromolecule and any metal nanoparticle. However, only a single species for the macromolecule (amidated PEI) and silver salts and copper salts for the metal nanoparticle have been explicitly disclosed.

The disclosure of a single disclosed species may provide an adequate written description of a genus when the species disclosed is representative of the genus. The present claim encompasses any and all branched amphiphilic macromolecules and any and all metal nanoparticles. There is substantial variability among the species of branched amphiphilic macromolecule and of a metal nanoparticles encompassed within the scope of the claims because PEI is only one molecule amongst an entire class of molecules, such as branched siloxanes/silanes, that can have widely differing structures and corresponding biological activities. With respect to the metal nanoparticle, alloys would be included in this genus as well as radioactive metals such as thorium and toxic metals such mercury thus supporting the wildly different physical properties and biological activities that these species can possess. Further, defining the branched amphiphilic macromolecule and of a metal nanoparticle in functional terms (amphiphilic only conveys that there is a polar water soluble group attached to a nonpolar water insoluble group and nanoparticle merely describes the size) would not suffice in the absence of a disclosure of structural features or elements of the branched amphiphilic macromolecule and of a metal nanoparticle that would have the stated function. Applicant is describing ***what the branched amphiphilic macromolecule and metal nanoparticle does*** rather than ***what they are***. Describing a compound by its functions will not substitute for written description of the structure of the compound. The invention should be explained in such a way as

to describe what the invention is, not what the invention does. Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Consequently, the Examiner notes that the claimed invention which is drawn to a genus of branched amphiphilic macromolecule and of a metal nanoparticle may be adequately described if there is a (1) sufficient description of a representative number of species, or (2) by disclosure of relevant, identifying characteristics sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. Here, the specification discloses only a single common structural feature shared by the members of the claimed genus, i.e., PEI for the macromolecule and silver or copper for the metal nanoparticles. Since the claimed genus encompasses branched amphiphilic macromolecules and of a metal nanoparticles yet to be discovered, the disclosed structural feature does not constitute a substantial portion of the claimed genus. Therefore, the disclosure of PEI and silver and copper does not provide an adequate description of the claimed genus.

Weighing all the factors, the breadth of the claims reading on branched amphiphilic macromolecules and of a metal nanoparticles yet to be discovered, the lack of correlation between structure and function of the branched amphiphilic macromolecule and of a metal

nanoparticle, level of knowledge and skill in the art, one of ordinary skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of branched amphiphilic macromolecules and of a metal nanoparticles. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least some of them will work. Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of branched amphiphilic macromolecules and of a metal nanoparticles to describe the claimed genus, nor does it provide a description of structural features that are common to the branched amphiphilic macromolecules and of a metal nanoparticlse. In essence, the specification simply directs those skilled in the art to go figure out for themselves the structure of the claimed branched amphiphilic macromolecule and of a metal nanoparticle.

The written description requirement is not satisfied.

Claim Rejections - 35 USC § 112

Claims 1-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the written description requirement has not been met, then one of ordinary skill in the art would not know which branched amphiphilic macromolecule and which metal nanoparticle to use and therefore one of ordinary skill in the art cannot make or use the invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites "...wherein the material of the product is non-resorbable or at least to some extent resorbable polymers." It is unclear to the Examiner if the claim is directed to non-resorbable polymers or partially resorbable polymers. In the event that Applicant intends the claim to read upon partially resorbable polymers it would then be unclear the metes and bounds of partially resorbable. The Examiner will examine the claim as it reads on any polymer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-14, 18, 20-22 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Aymonier et al. (Chem Comm 2002, 24, 3018-3019).

Aymonier et al. disclose hybrids of silver nanoparticles with amphiphilic hyperbranched macromolecules exhibiting antimicrobial properties (title and figure 1). The hybrids are made from amidated (palmitic acid or its methyl ester) polyethyleneimine with a degree of branching of about 60% and a degree of amidation of 40 to 50% (page 3018). The average MW for the

partially amidated polyethyleneimine was 5,000 g/mol (page 3018). Glass slides, a medical technology product, were coated with the polymer/silver nanoparticle hybrid where the nanoparticles were from 1-2 nm in size and up to 0.5 Ag ions per N atom (page 3018). Scattering experiments reveal structures with 3 nm size thus anticipating instant claim 13 (page 3018). It is the Examiner's position that the glass slide is sterilizable and reads on instant claim 20.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 20-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sanchez-Cortes et al. (Biomacromolecules 2002, 3, 655-660).

Sanchez-Cortes et al. disclose branched polyethyleneimine adsorbed on silver nanoparticles in glass capillary tubes (page 656, Experimental part and results and discussion). It is the Examiner's position that the glass capillary reads on a medical technology product and that the polyethyleneimine surrounds the silver nanoparticles to create a "capsule", in the absence of evidence to the contrary, and anticipates instant claims 1-3. It is the Examiner's position that the glass capillary is sterilizable. The hybrid complex is in contact with at least a portion of the surface of the capillary as well as being in the interior of the capillary thus meeting the limitations of instant claims 21-25. It is noted that Applicant teaches that glass slides will be

coated with the polymer nanoparticle hybrid merely by putting a drop of the hybrid on the slide and concentrating it [44].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (US 5,019,096) in view of Domb (US 6,127,448) and Sanchez-Cortez et al. (Biomacromolecules 2002, 3, 655-660).

Applicant claims a medical-technology product with a layer of a hybrid complex material composed of a branched amphiphilic macromolecule and of a metal nanoparticle, the layer having been provided at least on the surface and on the surface at least on a portion of the surface.

Determination of the scope and content of the prior art

(MPEP 2141.01)

The reference of Sanchez-Cortez et al. is described in detail above and that discussion is hereby incorporated by reference.

Fox et al. teach infection resistant medical devices such as catheters, implants (which can be ceramic materials), sutures, grafts, patches, wound dressings, and wound clips, comprising one or more matrix forming polymers (biodegradable polymers) and antimicrobial agents such as silver salts (Abstract and claims 58-60). Fox et al. thus fairly establish medical devices coated with polymers containing silver ions.

Domb teaches partially alkylated linear or branched polyethylene imine with C6 to C22 fatty chains for coating medical devices such as stents (a long lasting implant), catheters, grafts, metal and plastic devices (column 4, lines 1-67 and claims 1-7). It is the Examiner's position that "fatty chains" renders obvious fatty acids with C6 to C22 chains to one of ordinary skill in the art. Partially alkylated poly(amido amine) are also taught (claim 1). Alklyated PEI derivatives of 2000 and 5000 MW are taught (column 5, lines 45-48). Domb fairly establishes medical devices coated with modified polyamines such as partially alkylated linear or branched polyethylene imine with C6 to C22 fatty chains and partially alkylated poly(amido amine).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. The difference between the instant application and Fox et al. is that Fox et al. do not expressly teach a medical technology product composed of a layer of a branched amphiphilic

macromolecule and metal nanoparticle. This deficiency in Fox et al. is cured by the teachings of Domb and Sanchez-Cortez et al.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to make the medical device of Fox et al. with partially alkylated PEI entrapping silver nanoparticles, as suggested by Domb and Sanchez-Cortez et al., and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Fox et al. broadly teach using biodegradable polymers as the matrix for the silver ions and PEI is a biodegradable polymer. Sanchez-Cortex et al. provide the nexus teaching that silver nanoparticles adsorb to PEI. Domb provides the equivalence of using PEI or partially alkylated PEI (column 4, lines 1-17).

The degree of branching is intrinsic to the PEI and merely a design choice on the extent of branching of 20-90%, in the absence of evidence to the contrary. It is merely a matter of routine optimization of the materials as taught in the art to arrive at a ratio of silver atoms to nitrogen atoms from 1:2 to 1:10, in the absence of evidence to the contrary. In addition, since the materials are the same as instantly claimed then the hybrid complex would have a diameter of 0.5 to 10 nm or the narrower limitation of 2 nm, in the absence of evidence to the contrary. Incorporation of the "biocide" into the interior of a medical technology product is merely a design choice.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Summary: The art teaches coating medical devices with polymers containing silver ions. The art teaches PEI and alkylated PEI for coating medical devices. The art teaches silver nanoparticles adsorbed to PEI. One of ordinary skill in the art would expect a medical device coated with PEI or alkylated PEI containing silver nanoparticles to have a biocidal effect because such an effect is intrinsic to silver. From recent case law: "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." (KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. 550 U. S. ____ (2007) page 24).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600